Approved November 12, 2002
U.S. Environmental Protection Agency
EPA Science Advisory Board (SAB)
Executive Committee (EC)
October 1-2, 2002 Meeting

Summary Minutes of Public Meeting

Date: October 1-2, 2002 Meeting

Panel Members: See Roster - Attachment A.
Date and Time: 9 a.m. to 4:30 p.m., October 1, 2002 and 8:30 a.m. to 3:00 p.m., October 2, 2002 (See Federal Register Notice - Attachment B).
Location: Hotel Washington, Federal Room,
515 15th Street, NW, Washington, DC 20004

Purpose: The purpose of this meeting was to (1) take action on Committee reports including: a) Radiation Advisory Committee: "Underground Storage Tanks (UST) Cleanup and Resource Conservation and Recovery Act (RCRA) Subtitle C Program Benefits, Costs, and Impacts Assessment: An EPA Science Advisory;" b) Environmental Health Committee, Trichloroethylene (TCE) Review Panel: "Review of Draft Trichloroethylene;" and c) Executive Committee, Metals Assessment Panel report; (2) meet with Agency leaders; and (3) address matters of Board business: a) Finalizing the SAB project agenda for FY2003, and b) A Consultation on Data Quality and Reproducibility.

Attendees: Chair: Dr. William Glaze; EC Members: Dr. Henry Anderson, Dr. Maureen Cropper, Dr. Virginia Dale, Dr. Linda Greer, Dr. Philip Hopke, Dr. Janet A. Johnson, Dr. Roger Kasperson, Dr. M. Granger Morgan, and Dr. William H. Smith; Liaison with the Board of Scientific Counselors, Dr. Jerald Schnoor; SAB Members and Consultants: Dr. Rick Freeman , (by teleconference), Dr. John Maney, Dr. Valerie Thomas (by teleconference), Dr. Terry Young,

EPA SAB Staff: Mr. Robert Flaak, (DFO for the Panel), Dr. Angela Nugent, and Dr. Vanessa Vu.

Other Persons Attending: Speakers noted on the agenda or that addressed the Executive Committee: Ms. Linda Fisher, EPA Deputy Administrator, Dr. Paul Dugard, Director of Scientific Programs, Halogenated Solvents Industry Alliance, Inc.; Dr. Steve DeVito, Senior Scientist, Office of Environmental Information, USEPA; Mr. Kevin Bromberg, Chief Counsel for Energy and Environment, Office of Advocacy, Small Business Administration**;** Ms. Jane Luxton, Esq., King and Spaulding, Ad Hoc Metals Coalition**,** Mr. Jeffrey Worthington, Director of Quality, Office Environmental Information, USEPA, Dr. Bruce Rodan, MD, Medical Officer (Research), ORD National Center for Environmental Assessment, USEPA, Mr. Reggie Cheatham, Director, Environmental Analysis Division, Office of Environmental Information, USEPA, Dr. Denice Shaw, Office of Research and Development, USEPA, Dr. Paul Gilman, EPA Science Advisor, Assistant Administrator, Office of Research and Development, and other members of the public, as noted on the sign-in sheet (Attachment C).

Meeting Summary:

The discussion generally followed the issues and general timing as presented in the meeting Agenda (see Meeting Agenda - Attachment D). The meeting lasted until 4:25 on October 1, 2002 and until 2:30 p.m. on October 2, 2002.

OCTOBER 1, 2002

Welcome and Opening of the Meeting:

Dr. William Glaze, the Chair, opened the session at 9:00 a.m. thanking Committee members for attending. (Roster, Attachment A). He briefly reviewed the agenda (Attachment C) and alerted Members to an evening reception honoring SAB Members whose terms on the Board have ended and Agency staff receiving bronze medals.

Mr. Robert Flaak, Designated Federal Official (DFO) reviewed materials provided to the Members and the agenda for the meeting.

Members of the panel briefly introduced themselves and their institutional affiliations

Dr. Vanessa Vu, Director of the Science Advisory Board Staff Office, briefly reviewed staff office accomplishments since June: completing Fiscal Year 2002 reports underway; strengthening policies and procedures; managing the process for the Administrator's appointment of new membership for Fiscal Year 2003; obtaining additional resources for the staff; hiring new staff; developing an agenda of projects for FY 2003; designing an SAB accomplishments report; and designing a well-balanced SAB agenda for the new fiscal year.

Dr. Vu then mentioned that the Administrator would be reappointing two members to the Executive Committee whose terms had ended: Dr. Glaze and Dr. Philip Hopke. She welcomed the Administrator's two new appointments to the Board: Dr. Virginia Dale and Dr. Maureen Cropper. She acknowledged the contributions of departing Members, Dr. Terry Young and Dr. Robert Stavins.

She briefly described recent activities in the area of policies and procedures. She mentioned the publication of the brochure, *Overview of Panel Formation at the EPA Science Advisory Board*, and the new CD-ROM-based ethics training and new financial disclosure form, which will be used in FY 2003. The Office also has been seeking input from the Agency and public on policies and procedures and has a commitment to work on two areas. The first involves developing a brochure modeled on the National Academy of Sciences brochure "Roles of the Panel Chair," to describe the roles of different parties in the SAB advisory process (e.g., committee and panel chairs, panel members, EPA Staff, SAB staff, and the public), which highlights how the public can participate. The second area focuses on improved communication through the website and other mechanisms.

She introduced five new SAB staff who will be serving as Designated Federal Officers (DFOs): Mr. Fred Butterfield, (DFO for the Clean Air Scientific Advisory Committee); Mr. Daniel Fort (DFO for the Integrated Human Exposure Committee); Mr. Lawrence Martin (DFO for the Ecological Processes and Effects Committee) Dr. James Rowe (DFO for the Drinking Water Committee); and Dr. Suhair Shallal (DFO for the Environmental Health Committee). She reviewed committee assignments for current staff: Mr. Robert Flaak (DFO for the Executive Committee); Dr. Jack Kooyoomjian (DFO for the Radiation Advisory Committee); Mr. Thomas Miller (DFO for the Environmental Economics Advisory Committee and Research Strategies Advisory Committee); Dr. Angela Nugent (DFO for the Advisory Council on Clean Air Compliance Analysis); and Ms. Kathleen White (DFO for the Environmental Engineering Committee).

Dr. Vu also mentioned that in Fiscal Year 2003 there would be added resource support for SAB activities, including support for transcriptions of all panel and committee meetings and contract support for meeting logistics and travel, and improved accommodations for meetings.

General Discussion with the EPA Deputy Administrator

Ms. Linda Fisher, EPA Deputy Administrator, began her comments to the Executive Committee by complimenting the Committee and SAB Staff on recent procedural changes. She acknowledged the significance of actual implementation of these major changes.

She focussed her comments on a topic that the Executive Committee Members raised during their last discussion in March: how EPA uses documents produced by the SAB and how it benefits--or does not benefit--from them.

In her view, this topic was linked to two issues and potential opportunities. First, she saw benefit in the Board's using current panel activities to work with the Agency on creating the right "feedback loops" and "feedback mechanisms" that would provide the SAB with information with how the Agency is able to use SAB advice. Especially in cases, like the Metals Assessment Panel, which is providing early advice to the Agency on a cross-cutting, multi-media problem, continued frank interaction about how the Agency uses SAB input will be important

The second issue and opportunity related to her conversations with Dr. Glaze and Dr. Vu about their interest in a study of and potential redesign for the Board's structure. She viewed it as an excellent and timely exercise. A key question is whether the current structure and size of the Board "get in the way or enable the Board's moving with--or ahead of-- the Agency." She stated the importance of having the Board structured so that scientists can alert the Agency to issues they see.

She opened the discussion to Executive Committee Members' comments and questions.

The first set of questions concerned the set of issues that come to the Board for attention, and especially whether the "most critical things needing external review were coming to the Board." Some members acknowledged that they see science issues that should not have come to

the Board and also are sometimes surprised to learn of major science issues that should have come to the Board, but did not. Members emphasized that the Board provided insight and continuity that other peer review mechanisms do not, because standing committee members' long term knowledge of Agency programs help them provide more constructive advice.

Ms. Fisher asked about the kinds of topics most useful to bring to the Board. Executive Committee Members acknowledged that it may be useful to the Agency to bring controversial issues, but added that for the Board the key question is whether "there are important issues of science that need advice?" The SAB is interested in cutting-edge science, where there are methodological issues at stake that may be precedent setting.

Ms. Fisher then said that it may help the Board get the kinds of projects it's seeking to investigate the "track record" from the last two or three years to see what impact reports have had. It may help to learn the Agency's frank experience and reaction-- was the report language vague? Was the report timely? Were the documents helpful to people "on the line?"

An Executive Committee Member then cautioned that it was important to consider the SAB's work in the context of other kinds of peer review available to the Agency. There was a concern that the Agency may sometimes be "forum shopping" to get a favorable or less critical review. Are the functions of other forms of peer review clear? Are there criteria for different kinds of peer review?

The conversation then turned to the potential restructuring of the Board. An Executive Committee Member acknowledged the value of improving the Board's ability to respond rapidly to Agency needs and also asked whether there were additional issues to be taken up with realignment. What are the desired functions of the Board? Should its work be seen as primarily peer review? Or should the work be more anticipatory, more broad-gauge? If the Board sees issues cutting across different Agency work products, should it work on those issues?

Ms. Fisher stated that if the SAB just became just a peer review body, "we'd be missing a huge opportunity" because Board Members' varied experiences help the Agency take a "broader" and "more futuristic" view. Peer review is critical, particularly in controversial issues. But the role of the Board should not be limited to that. In the area of contaminated sediments and metals, the issues are larger than those posed by a single chemical. There is a need for early involvement on those kinds of multi-media issues. She believed SAB work on self-initiated projects was important and emphasized the need for the Board to work closely with Agency clients on those projects. "So however the Board is restructured, it has to allow for that." And internally, the Agency also needs to work to understand how it can make these self-initiated projects more useful.

Dr. Glaze added that the Board's current self-initiated project on ecological values depends on a strong relationship with Agency offices. In the case of that project, the Board has the direct support of two Agency offices and a process for working with them.

One Executive Committee Member pointed out that "rapid turnaround" projects sometimes result in limited advice. He suggested that the Board consciously ask whether projects can be addressed in a short time frame and plan for longer-term projects when necessary.

Ms. Fisher closed with some comments on the potential role for the Board in homeland security. She announced that the Agency's strategic plan in this area was to be announced tomorrow by Administrator on October 2, 2002. This plan outlines what Agency needs to do to build its capacity. The plan focuses primarily in the area of chemical and biological response, radiation and water infrastructure. It may suggest a role for the SAB in an area where the Agency may benefit from SAB advice. As EPA works with the new Office of Homeland Security, as the budget process becomes clearer, and the Agency's role "gels," then it would be appropriate to ask, "what could the role of the Board be?"

The Deputy Administrator concluded her remarks by giving reappointment letters to Drs. Glaze and Hopke an appointment letter to Dr. Dale and expressing her desire to work with the Executive Committee in the future.

Review of Draft SAB Reports

Dr. Glaze introduced the process for discussing the three draft reports under consideration, including the process for taking oral Agency and public comment.

The first draft report discussed was the "UST/RCRA BCI Review Panel: Underground Storage Tanks (UST) Cleanup and Resource Conservation and Recovery Act (RCRA) Subtitle C Program Benefits, Costs, and Impacts Assessments: An EPA Science Advisory Board Advisory."

Dr. Michael Shapiro, Principal Deputy Assistant Administrator for the Office of Solid Waste and Emergency Response, thanked the Board for the thoughtful, useful, and thorough analysis of UST and RCRA programs provided in the draft Panel Report. The review "accomplished what they had hoped"," delivered more than they expected, and will be used in making decisions about different approaches being considered for those programs. He expressed his confidence that advice from the review will have a major impact on how program will proceed, including "opening minds to additional ideas." He also noted that the panel's discussion of ecosystem valuation and the Agency's use of 95% confidence levels and dose response ""go beyond analysis of waste programs and present broad challenges to risk programs across the Agency."

He thanked the Board for its early advice on this project. He also mentioned that the Office of Solid Waste and Emergency Response will be seeking advice and input from the Board on another project that concerns the costs and benefits of Superfund.

Dr. Glaze then turned to the Panel Chair, Dr. Rick Freeman, who participated by teleconference, to introduce the draft panel report. Dr. Freeman mentioned that key findings were identified in the cover letter to the Administrator. One major suggestion pertained to how the Agency will do retrospective analysis, and whether such analysis should be designed across various elements of programs, instead of simply relating total benefits to total costs. He noted that the Agency's "attributes matrix" fell outside the normal framework for estimating health effects and their evaluation.

The Lead Discussant, Dr. Roger Kasperson commended the Panel for how it dealt with the four charge questions dealing with a rich array of issues. The review responded to the charge questions and gave good advice on wide array of topics. He noted a good use of evidence and supporting documentation. He also noted some areas where clarity and presentation could be improved. He suggested that the cover letter or Executive Summary should state the charge questions, at least in abbreviated form. He asked if topics raised under charge question 4 concerning sustainability had been fully answered.

Dr. Freeman responded that this problem might be addressed with language pointing to section 4.1. of the report and the comments on the attribute matrix. Dr. Kasperson agreed with this approach.

The Associate Discussant, Dr. Janet Johnson, then presented her comments. She suggested that it would be helpful to have the Agency's charge questions verbatim in the relevant sections of the report. Overall, she viewed the report as well written, but commented that there was "too much jargon" unexplained (an example was the term "convergent variability"). She suggested that there were several statements made in the body of report that might merit mention in the letter of the Administrator: (1) line 371-375, regarding use of conservative measures; and (2) lines 459-462 regarding equity issue of costs falling disproportionately on disadvantaged populations. She also requested a reference for the statement in line 1246-1247 regarding lower-income households having a greater likelihood of using well water. Dr. Freeman responded that he would modify the text on this point.

Other Executive Committee Members stated their appreciation for the attention to ecological aspects in the report. One semantic issue noted was the use of the term "ecosystems," where the intended meaning was more likely "ecological systems". One Member advised using the term "focal" species, instead of "rare and endangered species," and suggested the panel use terms consistent with the recent report of the Ecological Processes and Effects Committee on measurement of ecological conditions.

Action: The EC moved to accept the Panel report, *UST/RCRA BCI Review Panel: Underground Storage Tanks (UST) Cleanup and Resource Conservation and Recovery Act (RCRA) Subtitle C Program Benefits, Costs, and Impacts Assessments: An EPA Science Advisory Board Advisory*, contingent upon the Panel Chair's addressing minor editorial and language changes suggested by discussants (EC Action 1)

The second draft report discussed was the Environmental Health Committee Trichloroethylene (TCE) Review Panel: "Review of Draft Trichloroethylene Health Risk Assessment: Synthesis and Characterization-An SAB Report."

Dr. Glaze asked the Panel Chair, Dr. Henry Anderson to introduce the panel report. He began by recognizing the tremendous work of panel and the DFO. He noted that this project was the first controversial topic that had used the new panel formation process. The result was a very balanced panel. In the Panel's 2-day meeting, it was not able to address all the interesting and important issues that arose. The Panel made a decision early on not to take votes. If there was not clear consensus on an issue, different views of panel members were documented. Thus, the report

does not contain majority or minority opinions. The goal was to capture the range of scientific views and, in some cases, beliefs. Appendices to the document provide more science background on several issues. Key agreement points appear up front. The letter to the Administrator closes with the recommendation that the Agency needs to provide the pubic with the ability to reproduce the Agency's analyses. The Agency's TCE report relies on modeling that needs to be independently verified. The Agency relied also extensively on review articles, rather than underlying papers; Dr. Anderson indicated that the Agency needs to make ground rules clearer about if and when such an approach is appropriate. The Panel also made a number of structural recommendations to improve the Agency's report.

Dr. Anderson drew attention to three critical points of discussion within the panel: the cancer issue, sensitive subpopulations, and background exposures.

In summary, he stated that the Panel believed it had given the Agency its best possible advice and that Agency should move forward with the review.

Dr. Glaze then introduced Dr. Paul Dugard, Director of Scientific Programs, Halogenated Solvents Industry Alliance, Inc., who had requested time for oral comment. He distributed some short written comment to the Executive Committee (Attachment E). He acknowledged that his organization had substantial scientific disagreements with EPA's risk assessment, including the numerical bottom line, for both cancer and non-cancer. He also stated that the Panel's report is substantial and makes many excellent recommendations. In addition, he suggested that the Panel Report clarify language on Page 31 regarding one aspect of Charge Question 3.

The major focus of Dr. Dugard's remarks was "follow-up." He expressed surprise and disappointment that the Panel did not request an opportunity to review a revised version of the Agency report, given the extent of the revisions advised by the Panel review. He suggested that it would be appropriate for the Panel to review the revised document to determine if the panel's recommendations had been incorporated and if there were any major concerns about the revised version.

The Lead Discussant, Dr. Linda Greer, presented her comments. She viewed the document as a very good review of a complex document and noted that the Panel report was completed relatively quickly, in three months. She thought the draft report was well organized and included much useful commentary and information about TCE. In terms of structure, the letter and Executive Summary were not long and repetitive. She thought it effectively balanced providing information to the Agency and being direct in answering the charge question. She recommended that other SAB Panels consider using Appendices to provide important in-depth information that might otherwise "clutter-up" a report.

She raised two issues sparked by the report that she thought were especially important. She noted that the report called for the Agency to make modeling information publicly available for TCE. She noted a general need for the Agency to provide access to the information it uses for deriving cancer slope factors, because increasingly models used for risk assessment, especially physiologically based pharmacokinetic models, are not publicly available.

She also noted that the report raised several broad risk assessment issues that would be appropriate for future SAB reviews and panel activities. She suggested that it would be appropriate for the Board to have a process to systematically identify those top issues for future consideration. She suggested that it was inappropriate for the Panel to have addressed them fully within the context of the TCE assessment, but future Board attention to these issues could provide thoughtful analysis for longer-term attention to these major issues.

She also noted that she had given the DFO editorial suggestions for further improving the clarity of the document.

The Associate Discussant, Dr. Granger Morgan, then provided his comments. He characterized the Panel report as an impressive, extensive piece of work and an unusually careful and complete review. He read from written comments provided to the DFO and distributed to the Committee Members by email (Attachment F). He noted two important methodological recommendations in the report that merited attention from the Science Advisory Board: the need for improved methods, including methods to fairly represent a fuller array of uncertainty, to derive risk descriptors needed for different types of risk management analysis and decisions and the need to revisit the Agency's system of uncertainty factors.

Dr. Anderson then responded to the Discussants' comments. He noted that there was a tremendous wealth of data on TCE, but the data were not consistent. Uncertainty increased, rather than decreased, with additional information. Dr. Morgan commented that research in decision analyses shows that in early stages of analysis on an issue, additional data and analyses rarely reduce uncertainty.

Dr. Anderson then thanked the Discussants and agreed to incorporate their editorial comments. He mentioned that it would be relatively difficult to get Panel consensus on developing major new conclusions or even in adding specific detail on certain points, beyond the conclusions and views already expressed in the panel report. One Executive Committee Member asked if the letter might explain that the TCE review was exclusively human health-oriented and did not address ecological risks. Dr. Anderson agreed to include this language.

The Executive Committee then discussed several issues related to the TCE review that were broader in scope. Members discussed the merits of the Board's reviewing other risk assessments that raised issues similar to TCE to examine how those issues were resolved and how consistently. Members discussed the need to get an update on significant cross-cutting risk assessment issues (e.g., cancer guidelines, RfD/RfC methodology). Dr. Vu committed to planning an Agency update on these topics at the next Executive Committee Meeting.

Drs. Morgan and Greer agreed to draft a list of significant crosscutting risk assessment issues raised by the Panel report on TCE. This list would be drafted as a possible Commentary Letter to identify to the Administrator the need to give serious and ongoing attention to these issues. The list would also be considered as information to be considered in choosing future human health risk-related projects to be taken on by the Board. The Executive Committee Chair welcomed this commitment.

Commitment 1 Drs. Morgan and Greer agreed to draft a list of significant cross-cutting risk assessment issues raised by the Panel report on TCE. This list would be drafted as a possible Commentary Letter to identify to the Administrator the need to give serious and ongoing attention to these issues. The list would also be considered as information to be considered in choosing future human health risk-related projects to be taken on by the Board.

The Executive Committee then discussed whether the Board should officially request the opportunity to review the revised TCE report. It was pointed out that the Panel recommendations are very broad and in light of their scope, such a review might be appropriate. Another Member noted that the Panel could not come to consensus on many issues and that it might be unrealistic to think a revised risk assessment would satisfy the Panel. The Executive Committee asked the Staff Office Director to inform the Agency Leadership of these concerns and considerations and to ask them to taken them into account in their revisions of the TCE document. Dr. Vu agreed to take such action.

Action: The EC moved to accept the Panel report, *Environmental Health Committee Trichloroethylene (TCE) Review Panel: Review of Draft Trichloroethylene Health Risk Assessment: Synthesis and Characterization-An SAB Report*, contingent upon the Panel Chair's addressing the minor editorial and language changes suggested by discussants. (EC Action 2)

The third draft report discussed was the Executive Committee Metals Assessment Panel: "Review of Metals Action Plan."

Dr. Glaze introduced the Panel Chair, Dr. Valerie Thomas, who participated by teleconference call and gave an introduction to the draft panel report. Her major points follow. The panel reviewed the Agency's *draft Action Plan for Developing a Framework for Metals and Guidance for Characterizing and Ranking Metals*. The Panel commended the Agency for seeking advice at an early stage and agreed metals need to be handled differently from organic chemicals in a number of contexts. Dr. Thomas addressed a comment received concerning language about bioaccumulation and bioavailability in the Executive Summary, page 2 lines 29-34, and read to the Executive Committee revised language on that point. She noted also that the Panel recommended that stability and environmental residence time were more appropriate variables than "persistence." The Panel also asked The Agency to clarify its use of the words "hazards" and "risk."

The DFO, Mr. Bob Flaak acknowledged three sets of written comments received (Attachment G) and three speakers who requested time to present oral comments to the Executive Committee.

Dr. Steve DeVito, Senior Scientist, in the EPA's Office of Environmental Information provided oral comment. He requested clarification of language on bioavailability and bioaccumulation on page 6 of the draft, consistent with Dr. Thomas's comments on revised language in the Executive Summary. Dr. Thomas repeated her proposed revised language.

Mr. Kevin Bromberg, Chief Counsel for Energy and Environment, Office of Advocacy, Small Business Administration, spoke of the importance of addressing the language on bioaccumulation on line 29 of page 2. He emphasized that bioacummulation data can be

problematic for assessing metals hazards. He offered alternative language for the Panel and the Board to consider.

Ms. Jane Luxton, representing King and Spaulding, and the Ad Hoc Metals Coalition**,** briefly spoke and expressed concern for language in the draft (page 2, line 29-30) concerning bioaccumulation.

The Lead Discussant, Dr. Terry Young, then presented her comments. Her overall conclusion was that the review was of excellent quality, very well written and responded to each of the charge questions. She made several suggestions for consideration by the Panel to strengthen the Executive Summary: a) including lines 15-16 from page 8 and lines 2-7 on page 11 into item e; b) clarifying the language on bioaccumulation and ensuring that it is consistent throughout the Executive Summary and the report; c) clarifying the language in the Executive Summary and the report concerning where applications of data and bioaccumulation are appropriate and where they are not (e.g., generic metals hazard ranking, national rankings, such as water quality standards, use of BCF/BAF measures); d) expanding the discussion of environmental chemistry on page 6 .

She also advised that the letter to the Administrator expand on the importance of where "metals go" in the environment.

Dr. Young also suggested that section b) i) on page 2 reference a past review by the Ecological Processes and Effects Committee (EPEC) of EPA's proposed metals guidance for sediments, where EPEC took issue with EPA's decision not to address the metals component of suspended sediments in water. EPEC members recommended that EPA instead model the "compartments where metals travel and metals bioavailablity in those compartments." She advised that the Board communicate especially clearly on this point, because of the potential significance of a reservoir of chemicals with adverse effects that may become bioavailable in future.

The Executive Committee then briefly discussed the merits of calling the Agency's attention to the need to address previous EPEC advice in the draft Framework for Metals to be developed. The Executive Committee recommended that the SAB Staff Office plan to include this point in oral communication accompanying the report. Dr. Vanessa Vu agreed to take this action.

The Associate Discussant, Dr. Bill Smith, agreed with Dr. Young's characterization of the quality of the draft report. He thought it was readable and addressed the agency's charge questions well. He asked the Panel Chair whether the Panel discussed how the Agency bounded the category of "Metals" under consideration and asked whether that issue should be included. Dr. Thomas responded that the Panel itself discussed that issue and did not reach consensus about "what should be in and what should be out." Dr. Smith advised that such a discussion be included in the report. He also agreed with Dr. Young that a discussion of conceptual model development would be extremely useful.

Action:The EC approved the *Review of Metals Action Plan* report contingent on revised language developed in consultation with the Panel that is satisfactory to the Discussants. The Panel

Chair will draft revisions, circulate them to the Metals Assessment Panel, and then bring them back to the EC discussants for approval. (EC Action 3)

The Committee adjourned for lunch at 12:30 p.m. and reconvened at 1:45 p.m.

Consultation on Data Quality and Reproducibility

Dr Glaze introduced the consultation, recognizing the serious effort made by EPA Staff to respond to requirements under the Office of Management and Budget Information Quality Guidelines to meet standards of quality for information provided to the public by federal agencies. Dr. Glaze framed the consultation as a free-flowing discussion in which individual members of the EC offer their comments and consultation on issues presented by Agency Staff.

The consultation began with a brief presentation from EPA Staff, Mr. Jeffrey Worthington, Director of Quality, Office Environmental Information, and Dr. Bruce Rodan, MD, Medical Officer (Research), ORD National Center for Environmental Assessment (Attachment H)

Mr. Worthington thanked the EC for the expedited consultation. He described the Agency response to the OMB Guidelines, initial response provided to OMB on October 1, 2002, as an Agency-wide effort, involving EPA programs and regions. Information from the consultation would be used as guidance for the choices EPA will make in complying with OMB requirements.

Dr. Rodan framed the Consultation as a fairly narrow inquiry concerning the a higher standard of quality, i.e., "reproducibility", for information especially deemed by the Agency as "influential." In the consultation, EPA was primarily interested in Executive Committee Members' experience and standards used in the scientific community for "reproducibility." This higher standard of "reproducibility" for especially "influential" data was to be imposed in addition to basic standards of quality for all disseminated information (i.e., objectivity, utility, and integrity).

Several questions from the Executive Committee then followed as the Committee sought to understand the context for the consultation. Mr. Worthington stated that the consultation would be used in development of the Agency's next work product. He viewed the Agency's response to OMB as a "living document." He also informed the Executive Committee that the primary mechanism for coordination to date with other federal agencies was through OMB, although there had been an initial meeting at the National Institutes of Health, where multiple federal agencies participated.

Before addressing the specific charge questions of interest to the Agency, Executive Committee members discussed their understandings of the term "reproducibility" and their different views of its contributions to data quality. One view was that reproducibility did not seem like a quality control function. Reproducibility concerns only transparency about data or method. One might reproduce data that could be terrible or good data and so reproducibility itself doesn't determine whether the data or methods were good or bad. To make any judgement about the quality of data, one would need to make use of other criteria, such as robustness.

Members then discussed the scope of the reproducibility requirement. The Agency responded that it pertained to original and supporting data and analytical results, where the Agency deemed information to be "influential." Members commented that reproducibility of analysis was elusive, because data could be analyzed an infinite variety of ways. A Member of the EC stated that the recent work on the Harvard 6-city study, in his view, was more appropriately understood as a re-analysis, rather than as an example of reproducibility.

Members of the Committee then focussed on the specific charge questions presented by Dr. Rodan. The first concerned "What general 'types' of data can practicably be expected to be reproducible, given ethical, feasibility, confidentiality constraints?" The first point made by Members was that standards differ across different domains of science. Different disciplinary standards exist and are well understood within their disciplines. Some disciplines have much tighter norms than others do. In addition, in natural systems, "nothing is reproducible." Several members noted that it was important to distinguish between field data gathered from natural systems (which can not be reproduced, because natural systems are dynamic) and model data (which can be reproduced). One Board Member emphasized, however, that model data were not superior to field data, just because of reproducibility, and that good science required gathering actual data from natural systems.

Executive Committee Members emphasized the importance standards and protocols that exist in different fields for gathering data from natural events. Those standards don't result in "reproducibility," but they have a major importance to data quality. Members pointed out the significance of data obtained from accidents (for example from pesticide exposure, radiation exposure). Where there are good standards for collecting and analyzing data, good analysis and transparency, there are quality data, valuable data. By definition, these accidents, though, cannot be reproduced.

Several Members also pointed out that data about social systems were not reproducible. Also data about human exposure to toxicants and data about population genetic susceptibility are varied and not reproducible. The "more you know about these data, the more variable they are" and reproducibility seems more inappropriate as a standard for these kinds of data.

Executive Committee Members commented on norms related to reproducibility within the scientific community and professional journals. Peer review standards differ across different journals. In general, peer reviewers don't request or get access to original data. One Executive Committee Member noted that at his university, it is the policy that Ph.D. dissertation reviewers have access to proprietary data used in the dissertation, although these data may be protected from public disclosure. Another comment concerned researchers' attitudes to sharing data. Independent researchers may not feel comfortable with interest groups obtaining data they developed to reanalyze those data for a particular policy interest. A related issue concerned whether a data set can be mined. In general, it was stated that researchers want reasonable period of time to mine their own data to get additional results. One Member noted, however, that there may be a "pernicious" aspect to this lack of openness; researchers might mine data over time to get results they want. Other Members noted that there were several exceptions to the assumption that it was acceptable to delay releasing data in the academic world. One Member remarked that it is accepted practice in biological sciences to make new organisms or antibodies available on request. Another

Member noted that many federal agencies are requiring that ecological data collected through federal funding be put into repositories. She urged the Agency to consult with other Agencies on this topic and the reproducibility issue generally.

The discussion then turned to constraints on the kinds of data expected to be reproducible. In regard to contractual arrangements and access to "third party data" not developed by the Agency, one Member emphasized that bureaucratic standards and paperwork don't ensure quality and impose increasing burdens on researchers. Several Members focussed on the significant problems presented by confidentiality constraints on the availability and transparency for data. Where an entity collects and analyzes epidemiology data, it is critical to understand those data and how they were analyzed, if such data were to be used for setting standards or other regulatory purposes. Several Members expressed the view that confidential data presented significant problems for the Agency's use.

Several other Members discussed another dimension of the confidentiality issue. One Member pointed out that some data cannot be collected without making specific commitments to keep data confidential. Many human studies involve informed consent and up-front commitments to inform people about how the data they provide will be used. Also any data collected of this type involves a human factor and are context-dependent, and thus are not reproducible.

In terms of the specific Agency question about appropriate stipulations on researchers to make various kinds of data publicly accessible, several Members responded with specific suggestions. One was for the Agency to ask researchers specific questions about their data -- (e.g., to ask for lower quartile results or other specific statistical breakdowns) rather than request open access to all data, which might be perceived as a "fishing expedition." Reasonable requests need to be made of researchers. These requirements would be best made case-by-case and ground rules kept consistent through studies.

The Members closed their discussion of the first charge question in the consultation by expressing reservations about the general utility of the reproducibility requirement. One Member cautioned against setting up an ideal standard that could not be met. Other Members emphasized the limited value of reproducibility. Transparency or reproducibility was seen by some as a necessary component of the process of doing good science, but not sufficient to ensure good science. Other considerations seemed equally if not more important: Are the data really appropriate? Are there good methods for collecting them? Do the data answer questions? What is the quality of analysis? Focus needs also to be placed on the context in which the data is collected and used and the process and the quality of the process of testing and retesting understandings of multiple relevant data sets.

The Committee then turned to the second Charge Question: What general "types of analytic results can practicably be expected to be reproducible, given privacy, trade secrets, intellectual property and confidentiality protections? Several Committee Members spoke about the importance of openness and transparency about analytical approach used by the Agency. One Member's stated, "if you're not going to share your analytical approach, I'm not going to put much confidence in your data," and specifically included confidential data and proprietary analysis, not accessible to others. Another Member spoke of the "slippery slope" of confidentiality protections and the problems

presented when parts of the Agency, such as the Office of Pesticide Programs, rely on company confidential data and modeling. Another Member pointed out that it is the policy of the journal *Environmental Science and Technology* not to accept articles if authors won't make models available for analysis. Another Member pointed out the practical problems involved in researchers finding funding for proper documentation of models. She suggested that EPA might increase funding for this kind of effort and the Chair linked this concern to the SAB's general interest in strengthening the use of models at EPA.

The Committee then turned to the third charge question for the Consultation: When public access to data cannot occur, agencies are to perform especially rigorous robustness checks with degree of rigor left to the discretion of the agency in consultation with the scientific community? What does the scientific community consider as appropriate tests of robustness? The Committee generally questioned the Agency's use of proprietary or analytical methods that could not be made available to the public and felt that the Agency needs to move toward more transparency and narrow the set of cases where it could not make data and methods available to the public. One Member suggested that the Board "should go on record on this." One approach would be for the Agency prospectively to identify where it uses unvalidated models and proprietary analysis and explain why other kinds of information and analyses were not used.

The Members provided several ideas to help the Agency develop an approach to "robustness checks" for the narrow set of cases where such checks would apply. In general, they agreed that there was no way to provide an answer in the abstract. The relevant fields of environmental science are so broad and different and standards differ across them so much that the Board can only say "use best available scientific methods." One Member suggested that the Agency conduct a literature search of standards in different academic disciplines.

Several Members suggested that it might be useful for the Agency to return to the Board with specific information about the types of scientific issues, data and methods that raise the "robustness check" issue. Then the Board could respond with an appropriate response that would engage the experts knowledgeable in those areas. Indeed, it is the sense of the Executive Committee that the Agency and the SAB should develop a plan for ongoing review of this important area by the SAB.

Preparation for Next Fiscal Year

The SAB Staff Office provided material for discussion of Fiscal Year 2003 Projects for the next day. Mr. Flaak distributed spreadsheets organizing project requests and project sheets received for the next fiscal year and described how the SAB Staff Office had received requests from EPA programs and SAB self-initiated project requests and had discussed then with Assistant Administrators and the Agency's Science Policy Council.

Dr. Vu described the set of FY 2003 proposed projects assembled for Executive Committee discussion as an attempt to balance Agency high priority issues and SAB self-initiated projects, as well as balancing projects available to review with committee workload. She stated that in the

future she would like to have the Executive Committee view the SAB proposed projects within the context of EPA's overall peer review requests.

The Executive Committee adjourned for the day at 4:25.

OCTOBER 2, 2002

The Chair called the meeting to order at 8:30 a.m.. He welcomed a group of students from American University, Department of Government and gave a brief introduction to the Board, its history, and organization, including the role of the Executive Committee, and to the EPA Staff that supports the Board. He asked Executive Committee members to introduce themselves briefly and describe how their work in environmental protection relates to their service on the Board. After those introductions, the Executive Committee thanked Dr. Vu and the SAB staff for the previous evening's reception and for the presence of EPA senior leadership at the event.

Briefing on EPA's State of the Environment Report

Dr. Glaze introduced a briefing on EPA's State of the Environment Report from EPA staff, Mr. Reggie Cheatham, Director, Environmental Analysis Division, Office of Environmental Information (OEI) and Dr. Denice Shaw, Office of Research and Development (ORD). Dr. Vu informed the EC that the Agency has requested that the SAB review the State of the Environment Report as a FY 2003 project.

Mr. Cheatham provided an overview of EPA's effort to develop the report, which is focussing on the key issue of data gaps. The first product of the OEI/ORD partnership to develop the report will be a draft to begin dialogue with public and especially state and federal partners. He envisioned two products: a public report for informed public and a technical support document. He emphasized the importance of the documents being understandable and scientifically credible.

Dr. Shaw distinguished the EPA report effort from the recent publications of the National Research Center, Heinz Center, and the SAB's EPEC. EPA intends not only to describe known information about environmental indicators, but also to characterize what is not known or understood, and is needed to strengthen the knowledge base on environmental indicators. The EPA report will have two key chapters on human health and ecological conditions. It will also have chapters on air, water, and land.

To date, EPA has consulted with experts to discuss the Agency's general strategy and approach and it has asked reviewers to discuss the set of indicators the Agency plans to use -- to determine if and how those indicators are to be used.

Mr. Cheatham discussed the status and timing of release of the EPA draft report. He stated that the a draft would be shared with senior managers in a few weeks, and then Agency staff will incorporate their comments. After those revisions are done, EPA intends to submit the draft technical support document to the SAB when the Agency is ready to release the document to the public. Dr. Vu added that she envisions that the SAB would review the technical document first (in the 2nd quarter of FY2003), and then review the public document in the 4th quarter of FY 2003.

The EC Chair opened the discussion to Executive Committee questions and comments. One Member suggested that EPA involve experts in multi-attribute decisions and decision-analytic processes (such as Henry Willis, Mike DeKay, and Tim McDaniels) so that the EPA report will have clear summaries and conclusions. Another member asked whether the report will track trends over time, set targets, and make comparisons to other countries. Dr. Shaw responded that EPA is not developing new indicators and is instead relying on existing ones for the planned report for FY2003. The planned report will not set targets, but instead make a case for setting them in the future. The report will include time trends and will need to choose benchmarks for those trends.

In a response to a question about the structure of the report, Dr. Shaw responded that the report will represent national indicator information. Because there are limited national data, questions about sampling, regional regimes, and sampling units and scaling have become important.

Another Member asked whether and to what extent will the report provide analysis of sources and driving forces of environmental problems and how they're changing? Mr. Cheatham responded that the report will contain information on historical trends in each chapter. It will emphasize the Agency's mission and statutory mandates. Where EPA is able to provide information for international comparisons, it will provide that context. It will not have a heavy emphasis on transboundary issues, although it will reference other reports at appropriate places, for example, the recent NAFTA report. The Agency is constrained by its goal of keeping the public report in the 80-page range.

In regard to causal linkages, Dr. Shaw stated that available data make it difficult to define such relationships. EPA has ambient information, but lacks much information about human health and ecological effects that would allow it to detail those relationships. Mr. Cheatham stated that the report would indicate clear links in cases where sources have been controlled or eliminated, such as DDT and effects on bald eagles and their offspring.

Mr. Cheatham said that the report would be used within the Agency as input for a strategic plan to work with other entities, especially states and other federal agencies to obtain data to strengthen the knowledge base for environmental indicators.

One Member emphasized the importance of EPA developing the analytical component of its State of the Environment Report. He noted that a comparison of such reports by other countries shows that analytical reports are of higher quality than reports that are entirely descriptive.

The outgoing chair of EPEC complimented EPA on the plans for the report. She commended the Agency's choice of information to include in the report, since it includes information on topics recognized as of general interest and also information to raise awareness about environmental conditions. She saw great value in the organizational structure of the report, which includes two key chapters on ecological condition and human health, and which does not simply showcase Agency programs. She expressed appreciation for the Agency's use of the advice provided by the recent EPEC report on environmental conditions.

A Member of the Executive Committee asked how the report planned to address issues of uncertainty in understanding the state of different aspects of the environment. She asked how the Agency plans to address, for example, trends in trends in asthma and how it will draw links with exposure to environmental contaminants like ozone. Dr. Shaw responded that the Agency has focussed on the issue of uncertainty regarding that particular example. It plans to include discussions in the report about uncertainties in counting asthma cases (e.g., cases of morbidity or mortality); uncertainties associated with links to exposure; and uncertainties about the mechanisms of asthma. Both the air chapter and the health chapter will describe the uncertainties. The report will have a double focus: on what is known and what is uncertain.

The Committee then asked whether the Agency will identify critical research gaps, as a key to developing an action plan for filling those gaps. Dr. Shaw responded that the Agency envisions the next step being a strategic plan for filling data gaps.

The Chair of the Environmental Health Committee commended the Agency on its approach and expressed his Committee's interest in assisting the effort. A key issue in public health is how to influence the nation's health database and how to develop a holistic approach to health and the environment. He saw opportunities in EPA's future use of environmental health indicators from the Centers for Disease Control (CDC) and state health departments. "There is a wealth of information but everyone is cobbling it together." He suggested that the Board might help EPA work with health experts at other Agency. Mr. Cheatham responded that EPA is starting to work with state health agencies, the National Cancer Institute, and CDC. The Council on Environmental Quality is facilitating Agency access to economic and other social indicators.

The Executive Committee concluded the briefing with a discussion of some specifics regarding the Board's review of the Agency's documents on this subject planned for later in the Fiscal Year. The Agency intends to charge the Board with a full review of a draft document before it goes final. The Agency would like a rigorous review by a multi-disciplinary panel. The scope of the review would include technical issues such as data collection, sampling, choice of indicators, analysis, and appropriate presentation through visual or other means. The Agency desires SAB advice to improve the quality and credibility of the report. Members of the Board added that it might also be useful to the Agency for the Board to identify critical data gaps, as it reviews the Agency's draft documents. Such information could assist the Agency in developing its strategic plan.

SAB Operations Plan for FY2003

The Executive Committee Chair identified the purpose of the discussion and approval of the operating plan by Members of the Executive Committee. Dr. Vu expressed interest in Members comments and suggestions, especially about assignment of projects and committee workload. She assured Members of support for these projects from Agency senior leadership and sufficient resources to support them.

The first set of projects discussed were projects assigned to ad-hoc Panels of the Executive Committee, and then projects assigned to other SAB Committees were discussed. The full

discussion was interrupted by a General Discussion with Dr. Paul Gilman and a Lunch Break, but the action items from the full discussion of the Operating Plan are presented below.

Project 03-11 Data Reproducibility: Dr. Vu will request feedback from Agency staff regarding their understanding of the consultation.

Project 03-13 Multimedia, Multipathway, and Multireceptor Risk Assessment (3MRA) Model: SAB Staff will follow the new panel formation process and expects to involve many members of the previous Environmental Models Subcommittee.

Project 03-06 Valuing the Protection of Ecological Systems and Services: The DFO will brief Dr. Cropper, the new Chair of the Environmental Economics Advisory Committee (EEAC), about the background of the project and set up an ongoing mechanism to keep the Chairs of the Advisory Council on Clean Air Compliance Analysis, EEAC, and EPEC informed about the progress of this project. : Next steps involve choosing a chair, issuing a "Widecast" Federal Register, and organizing a planning meeting. A workshop is likely to happen next spring.

Project 03-31 Computational Toxicology: EC Members directed the staff to ensure that the charge questions for this project included a discussion of access to and the role of proprietary models, because the field of computational toxicology is likely to involve the use of such models.

Project 03-17 State of the Environment Report: Dr. Vu will review an early draft of the technical document and consider how to structure and sequence the Agency review, in response to suggestions that EPEC, the Environmental Health Committee, and the Integrated Human Exposure Committee review the document before it comes to the EC. Dr. Vu to lead a discussion of a proposed plan to review the technical discussion at the December EC Teleconference or through some other mechanism before the teleconference.

Project 03-07 Determining Economic Benefit from Violator's Illegal Competitive Advantage (EEAC Project): SAB Staff to consider lawyer's involvement in panel.

Project 03-26 All Ages Lead Model (IHEC Project): SAB Staff to seek expert with knowledge about public perception research.

Project 03-09 Dose-Response Commentary [Radiation Advisory Committee (RAC) Project]): SAB Staff to develop a one-pager for this activity.

Project 03-05 Advisory on Draft Multi-Agency Radiological Survey & Site Investigation Manuel (MARSSIM) Supplements (RAC Project): SAB Staff to consider splitting this into two related projects: a consultation and advisory on slightly different topics.

Project 03-03 Presidential S&T Budget Request (Research Strategies Advisory Committee Project): SAB Staff to check with Congressional Staff and other appropriate customers about whether the Board's mechanisms are designed to work at a sufficiently early stage to give effective advice.

Project 03-25 Air Quality Criteria for Ozone and Project 03-07 Consultation on Ozone Research Strategy [Clean Air Scientific Advisory Committee (CASAC) Projects]: SAB Staff to investigate whether these are "likely to be bumped to FY04" and how to involve a liaison with EPEC

Project 03-18 Multi-Year Plan for Particulate Matter (CASAC Projects): SAB Staff to investigate and report back about how this project will relate to CASAC's review of the PM Research Strategy and how it will relate to the Staff Paper for PM

Project 03-12 Ambient Air Monitoring Stratgy: SAB Staff to ensure CASAC subcommittee has a link to the SAB past committee on the National Air Toxics Assessment and the Council's Air Quality Modeling Subcommittee.

The Executive Committee then raised issues regarding activities not included in the Operating Plan and the following action items were identified.

a. Residual Risk: SAB Staff Office will investigate the status of this activity and SAB review.

b. Mercury Research Strategy and Risk Management Activity: Dr. Vu will provide for an update for the EC regarding the Agency's Mercury Research Strategy and related risk management activities.

c. Risk Management and Risk Reduction: Dr. Glaze will consult with the Chair of the Environmental Engineering Committee (EEC) about potential EEC activities involving risk management and risk reduction, such as industrial ecology, pollution prevention, environmental management systems, and control technology. Dr. Vu will contact leads for pollution prevention in EPA's Office of Research and Development and invite them to give the EC an update on Pollution Prevention Research and Science.

e. Several topics were identified for which there was no "project sheet" and entry provided in the Operating Plan for consultation with the Agency's Science Policy Council and the EC. The following action items related to development of "project sheets" for consideration were discussed:

i. Ecological Chapter of the "Integrated Risk Project (IRP):" SAB Staff and EPEC chair will develop a one-pager to describe project to finalize ecological work from the IRP never published.

ii. Results of the Risk Reductions Options Subcommittee of the "Integrated Risk Project:" Ms. Kathleen Conway of the SAB Staff to develop a one-pager to describe project to finalize this work

iii. Landscape work of the National Exposure Research Laboratory, (Las Vegas): Mr. Flaak to follow up on a request from the Chair of EPEC to check whether the laboratory would like an EPEC review and whether they would resubmit a project sheet for that activity

iv. Economics Projects: SAB staff to work with Dr. Cropper to coordinate with the Director of the National Center for Environmental Economics to identify potential projects for the EEAC for FY 04.

In the course of discussion of specific projects, the Executive Committee raised several issues of a scope broader than any single project. The SAB Staff Office committed to address the following general issues raised in the EC Discussion:

a. SAB staff will consider the issue of appropriate balance between Members and Consultants as future panels are assembled to address topics of major significance to the Agency.

b. SAB Staff to develop and communicate a clear approach to conflict of interest and appearance of conflict for reviews of research strategies.

c. SAB Staff to provide the EC with information about how IRIS chemicals in general will be peer reviewed and how they use mechanistic analysis

The Executive Committee then discussed the broad issue of how the Board might "get the most important project." Dr. Glaze encouraged Executive Committee Members to develop self-

initiated projects and to work with clients in the Agency to "nurture" those projects. He asked Members to work with SAB Staff to develop project sheets, with the appropriate kinds of background information, describing self initiated projects. He asked them to send them on an ongoing basis to the SAB Staff for consideration. He asked that all Members use this process and communicated to Executive Committee Members not present at the meeting.

General Discussion with Dr. Paul Gilman

Dr. Glaze introduced Dr. Paul Gilman, EPA Science Advisor and Assistant Administrator, Office of Research and Development. He briefly described his professional background and role at EPA where he not only heads the Office of Research and Development, but also provides to the Agency generally about Agency science and use of science.

He began the discussion with several considerations for the Board's future work. He suggested that the Board adopt a structured process for getting feedback about how the SAB work is utilized by the Agency. He encouraged the Executive Committee to have a senior manager speak at every meeting about how SAB advice has been useful or not. He also suggested that the Board consider surveying customers at the program level to enquire how the Board "can do better systematically."

He also suggested that the Board consider the National Research Council Report Review Committee as a model for reviewing SAB work. He described the value of the committee in QA/QC and its focus on whether draft reports address the statement of task and were appropriately responsive reviewers.

He also informed the Executive Committee that he would be asking for help from the SAB in applying the Board's current model of addressing conflicts of interest and balancing panels to other federal advisory committees throughout the Agency. He also plans to apply relevant parts of the SAB process to peer review mechanisms across the Agency. He informed the group that he was planning a pilot in ORD.

Dr. Gilman invited questions and comments from SAB Members. In regard to the topic of the appropriate balance of core research and problem driven research in ecological sciences and appropriate the balance between ecological research and human health research, Dr. Gilman responded that the Agency has not communicated well the success of programs like EMAP, which he viewed as a core program successful in putting real tools in the hands of users at the federal and state levels. He sees an increasingly short time frame between development of scientific insights at the bench level and application of those insights to problems. He also affirmed that ecological health and human health were goals so closely related, they might be considered one goal.

In response to a question about STAR grant fellowships, Dr. Gilman updated the Executive Committee on Congressional review of that program (Senate restored it; House has yet to act), which may result in restoration of funds for one year. He expressed the view that he wished Congress had focussed more broadly on the STAR grant program and its quality, rather than the narrow issue of the fellowship.

Dr. Gilman then addressed a question about Agency modeling and the use of proprietary software that involves "black boxes" preventing understanding and access to data and methods. He stated that the Agency's Committee on Regulatory Evaluation and Modeling should address this issue and that the Board should be involved at an early stage of addressing the issue.

He commented briefly on the Agency's computational toxicology program. He praised the infrastructure built by his predecessors, Drs. Huggett and Noonan, in reorganizing the Office of Research and Development (ORD) and organizing science activities around risk. On coming to ORD, he found a structure of laboratories and programs receptive to genomics and computational toxicology. The program is currently identifying partners from other federal agencies and outside research organizations for the effort. The Agency is developing an interim policy on genomics. He also mentioned the importance of involving the regulated community and public interest groups in understanding and supporting what the new approaches can offer regulatory programs.

The conversation then turned to the importance of social and behavioral sciences in environmental protection. One Executive Committee Member asked how the Agency is preparing to address the increasing importance to environmental management of understanding basic social structures, economics, cultural attitudes, and issues in human behavior. He pointed out the Agency's limited capability in social sciences beyond economics and asked, "what is going on at the Agency to build scientific capability in this area? Dr. Gilman responded that the major Agency vehicle is the STAR grants. He acknowledged the importance of the social sciences for risk management, communication about risks and environmental issues, and dealing with the public. He suggested building partnerships with Agency programs on these topics, so that SAB advice in this area is internalized.

Dr. Morgan then asked Dr. Gilman about ORD's response to a FY 2001 SAB Report on science and stakeholder involvement (EPA-SAB-EC-COM-01-006, Improved Science-Based Environmental Stakeholder Processes), which included several recommendations for expanding the social science and research base in the Agency. Dr. Gilman agreed to follow up on this request and inform the Board about what has been done in response to the report.

Another Member asked about how EPA chose peer review for different risk assessments and the mechanisms in the Agency to prevent "forum shopping" and inconsistencies in how peer reviews are written on conducted. Dr. Gilman responded that the Agency's peer review policy takes a tiered approach. The "more important topics in terms of economic impact and public policy interest find their way to groups as visible as the Board." In response to a specific question about Agency work on a new approach to RfD/RfCs, Dr. Gilman informed the group that the next step for the Agency's RfD/RfC "White Paper" will be further development by the Agency's Risk Assessment Forum. In his view, the Forum effort should give an opportunity for SAB involvement and potential joint effort on this topic.

The Chair of the Executive Committee ended the discussion with thanks to Dr. Gilman and an invitation to attend future SAB Executive Committee Meetings.

The Committee adjourned for lunch at 11:30 a.m. and reconvened at 1:00 a.m..

General Committee Discussion on SAB Internal Business

Dr. Glaze initiated a discussion with Executive Committee Members regarding a proposed SAB Realignment. He asked them to consider the draft "Charge to a Sub-Committee of the Science Advisory Board Executive Committee to Reexamine the Structure, Organization and Composition of the EPA SAB." The Goal of the subcommittee was to examine how the Board should be reconfigured to "excel" in its work and to provide a plan for reorganization plan to the Administrator so it can be by October 1, 2003. Dr. Vu reiterated the support from the Agency leadership for this initiative.

The Executive Committee accepted the proposed Charge. Members made several suggestions for the work of the Subcommittee to be appointed by the Executive Committee Chair: (1) identify clearly specific problems that need to be addressed by a reorganization; (2) report frequently about the progress of their work; and (3) identify practical options early in the process.

The Executive Committee also briefly discussed a proposal for a pilot for a new approach to Executive Committee Review of SAB Reports. The Executive Committee Chair proposed that design of and plans for this pilot be part of the Subcommittee he would create. This approach was accepted by Members of the Executive Committee.

Conclusion of the Meeting

The Chair adjourned the meeting with thanks to Members and Staff and acknowledgement of the value and effectiveness of their work together.
At 2:30 p.m., Dr. Glaze adjourned the meeting.

Respectfully Submitted:

/ Signed /

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Robert Flaak
Designated Federal Official

Prepared by:

/ Signed /

_____
Angela Nugent
Special Assisant

Certified as True:

/ Signed /

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William H. Glaze
Chair

Attachments:

Attachment A: Roster of Executive Committee
Attachment B: Federal Register Notice
Attachment C: Sign-in Sheet
Attachment D: Meeting Agenda
Attachment E: Written comments from Dr. Paul Dugard, Director of Scientific Programs, Halogenated Solvents Industry Alliance, Inc.
Attachment F: Vettor's comments by Granger Morgan on the SAB Draft Report "Review of Draft Trichloroethylene Health Risk Assessment: Synthesis and Characterization"
Attachment G: Written Comments Received on the Metals Assessment Plan Draft Report
Attachment H: Powerpoint Slides. Consultation with EPA's science advisory Board: "Reproducibiity" under the OMB *Information Quality Guidelines*. October 1, 2002.